

1 EDWARD R. REINES (Bar No. 135960)
2 edward.reines@weil.com
3 DEREK C. WALTER (Bar No. 246322)
4 derek.walter@weil.com
5 MICHELE A. Gauger (Bar No. 281769)
6 michele.gauger@weil.com
7 WEIL, GOTSHAL & MANGES LLP
8 Silicon Valley Office
9 201 Redwood Shores Parkway
10 Redwood Shores, CA 94065
11 Telephone: (650) 802-3000
12 Facsimile: (650) 802-3100

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14 Attorneys for Plaintiffs
15 VERINATA HEALTH, INC.

16 and

17 THE BOARD OF TRUSTEES
18 OF THE LELAND
19 STANFORD JUNIOR
20 UNIVERSITY

21
22 UNITED STATES DISTRICT COURT
23
24 NORTHERN DISTRICT OF CALIFORNIA

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28 VERINATA HEALTH, INC.,

Case No. 3:12-cv-05501-SI

and
16
17
18 THE BOARD OF TRUSTEES OF THE
19 LELAND STANFORD JUNIOR
20 UNIVERSITY,

**FIRST AMENDED COMPLAINT FOR
PATENT INFRINGEMENT**

21 Plaintiffs,

JURY TRIAL DEMANDED

22 v.

23 ARIOSA DIAGNOSTICS, INC.,

24 and

25 LABORATORY CORPORATION OF
26 AMERICA HOLDINGS,

Defendants.

1 Plaintiffs Verinata Health, Inc. (“Verinata”) and The Board Of Trustees Of The
 2 Leland Stanford Junior University (“Stanford”), for their complaint against Defendants Ariosa
 3 Diagnostics, Inc. (“Ariosa”) and Laboratory Corporation of America Holdings (“LabCorp”)
 4 (collectively “Defendants”), allege as follows:

5 **NATURE OF THIS ACTION**

6 1. This action arises under 28 U.S.C. §§ 1331 and the United States Patent
 7 Act, 35 U.S.C. § 100 *et seq.*

8 2. Verinata and Stanford bring this action to halt Defendants’ infringement of
 9 Verinata’s rights under the Patent Laws of the United States, 35 U.S.C. § 1, *et. seq.*..

10 **PARTIES**

11 3. Verinata is a corporation organized and existing under the laws of the State
 12 of Delaware, with its principal place of business at 800 Saginaw Drive, Redwood City, California
 13 94063. Verinata was formerly known as Artemis Health, Inc. (“Artemis”). Verinata’s research
 14 and clinical facilities are located in Redwood City, California. Verinata is the owner of U.S.
 15 Patent No. 8,318,430 (“the ’430 patent”). Verinata is also an exclusive licensee of U.S. Patent
 16 No. 8,296,076 (“the ’076 patent”) in the field of genetic analysis by nucleic acid sequencing.

17 4. Stanford is a trust possessing corporate powers that is organized under the
 18 laws of California, with a principal place of business at the Office of the President, Building 10
 19 Main Quad, Stanford, California 94305. Stanford is the patent owner and licensor for the ’076
 20 patent and is joined in the infringement action for this patent because it is a necessary party.

21 5. On information and belief, Ariosa is a company organized and existing
 22 under the laws of Delaware, with its principal place of business at 5945 Optical Court, San Jose,
 23 California 95138.

24 6. On information and belief, LabCorp is a company organized and existing
 25 under the law of Delaware, with its principal place of business at 358 South Main Street,
 26 Burlington, North Carolina 27215.

27 7. Defendants have, and have had, continuous and systematic contacts with
 28

1 the State of California, including this District. For instance, Ariosa has acknowledged in *Ariosa*
 2 *Diagnostics, Inc. v. Sequenom, Inc.*, Civil Action No. 11-03691 (N.D. Cal. Dec. 19, 2011) that it
 3 “currently is, and has been, using the Aria Test in this District to conduct clinical studies in order
 4 to validate the performance of the test in detection of fetal chromosome abnormalities.”
 5 Likewise, LabCorp maintains numerous laboratory facilities in this district. On information and
 6 belief, Defendants have purposefully directed a broad range of business activities at this District,
 7 including among other things research, sales, blood collection and processing, and related
 8 services. On information and belief, residents of this District have used services sold by or from
 9 Defendants.

10 **JURISDICTION AND VENUE**

11 8. This action arises under the Patent Laws of the United States of America,
 12 35 U.S.C. § 1 *et seq.* This Court has federal question jurisdiction under 28 U.S.C. § 1331 and 28
 13 U.S.C. § 1338(a) because this is a civil action arising under the Patent Act.

14 9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) because
 15 a substantial part of the events giving rise to Verinata and Stanford’s claim occurred in this
 16 District and because Defendants are subject to personal jurisdiction in this District.

17 **INTRADISTRICT ASSIGNMENT**

18 10. Pursuant to Civil Local Rules 3-5(b) and 3-2(c), because this action is an
 19 intellectual property action, it is properly assigned to any of the divisions in this District.

20 **BACKGROUND**

21 11. Since its founding, Verinata’s activities have focused on developing and
 22 offering non-invasive tests for early identification of fetal chromosomal abnormalities using its
 23 proprietary technologies. In early 2012, Verinata began offering such a test, the verifi® prenatal
 24 test, on a commercial basis. The verifi® prenatal test employs novel techniques to analyze cell-
 25 free DNA circulating in the blood of a pregnant woman by DNA sequencing in order to
 26 determine whether a fetus is at risk of having an abnormal number of chromosomes (sometimes
 27 referred to as “aneuploidy”).

28

1 12. In or around May 2012, Ariosa and LabCorp began offering a commercial
 2 non-invasive prenatal test for Down syndrome, which they referred to by the trade name
 3 Harmony™ Prenatal Test. As Ariosa stated in a press release dated May 7, 2012, “[t]he Harmony
 4 Prenatal Test, which detects common fetal trisomies such as Trisomy 21 (associated with Down
 5 syndrome), will be offered through LabCorp and will be available at its 1,000+ patient service
 6 centers.”

7 13. The press release goes on to explain that the Harmony™ Prenatal Test “is
 8 performed using a simple maternal blood draw taken at a doctor’s office or patient service
 9 center.” Technical literature describing the technology underlying the Harmony™ Prenatal Test
 10 (which Ariosa identifies in a section of its website entitled “ABOUT THE SCIENCE”) explains
 11 that the method involves *inter alia* sequencing predefined subsequences of maternal and fetal
 12 DNA present in the maternal blood draw. *See, e.g.*, Sparks, A.B., Struble, C.A., Wang, E.T.,
 13 Song, K., Oliphant, A., Non-invasive Prenatal Detection and Selective Analysis of Cell-free DNA
 14 Obtained from Maternal Blood: Evaluation for Trisomy 21 and Trisomy 18, *Am. J. Obstet.*
 15 *Gynecol.* (2012). In view of this description, on information and belief Defendants’ Harmony™
 16 Prenatal Test infringes the ’076 and ’430 patents directly and indirectly.

17 14. On information and belief, Defendants have and continue to perform the
 18 Harmony™ Prenatal Test on samples of maternal blood. Likewise, on information and belief,
 19 LabCorp has and continues to encourage Ariosa to perform the Harmony™ Prenatal Test,
 20 intending that Ariosa perform the test.

21 15. On information and belief, LabCorp has and continues to supply to Ariosa
 22 material components of the Ariosa™ Prenatal Test having no substantial non-infringing use.

23 **COUNT I (by Verinata and Stanford)**

24 **Infringement of U.S. Patent No. 8,296,076**

25 16. Plaintiffs re-allege and incorporate by this reference the allegations
 26 contained in paragraphs 1 through 15 above as relevant to this count.

27 17. On October 23, 2012, the United States Patent and Trademark Office duly
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1 and legally issued the '076 patent, entitled "Noninvasive Diagnosis of Fetal Aneuploidy By
 2 Sequencing."

3 18. Stephen Quake, Ph.D., and Hei-Mun Christina Fan, Ph.D., are the sole and
 4 true inventors of the '076 patent. By operation of law and as a result of written assignment
 5 agreements, Stanford obtained the entire right, title, and interest to and in the '076 patent.

6 19. Pursuant to license agreements Verinata entered into with Stanford,
 7 Verinata obtained an exclusive license to the '076 patent in the field of genetic analysis by
 8 nucleic acid sequencing.

9 20. On information and belief, Defendants have and continue to directly
 10 infringe the '076 patent by practicing one or more claims of the '076 patent by, including without
 11 limitation, performing the Harmony™ Prenatal Test, and will continue to do so, unless and until
 12 enjoined by this Court.

13 21. On information and belief, LabCorp has and continues to induce others to
 14 infringe the '076 patent by, including without limitation, encouraging Ariosa to perform the
 15 Harmony™ Prenatal Test, and will continue to do so, unless and until enjoined by this Court.

16 22. On information and belief, LabCorp has and continues to contributorily
 17 infringe the '076 patent by, including without limitation, supplying to Ariosa material
 18 components of the Harmony™ Prenatal Test having no substantial non-infringing use, and will
 19 continue to do so, unless and until enjoined by this Court.

20 23. Defendants' infringement of the '076 patent has injured Plaintiffs in their
 21 business and property rights. Plaintiffs are entitled to recovery monetary damages for such
 22 injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

23 24. Defendants' infringement of the '076 patent has caused irreparable harm to
 24 Plaintiffs and will continue to cause such harm unless and until their infringing activities are
 25 enjoined by this Court.

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COUNT II (by Verinata Only)

Infringement of U.S. Patent No. 8,318,430

25. Plaintiff Verinata re-alleges and incorporates by this reference the allegations contained in paragraphs 1 through 24 above as relevant to this count.

26. On November 27, 2012, the United States Patent and Trademark Office duly and legally issued the '430 patent, entitled "Methods of Fetal Abnormality Detection."

27. Yue-Jen Chuu, Ph.D., and Richard P. Rava, Ph.D., are the sole and true inventors of the '430 patent. By operation of law and as a result of written assignment agreements, Verinata obtained the entire right, title, and interest to and in the '430 patent.

28. On information and belief, Defendants have and continue to directly infringe the '430 patent by practicing one or more claims of the '430 patent by, including without limitation, performing the Harmony™ Prenatal Test, and will continue to do so, unless and until enjoined by this Court.

29. On information and belief, LabCorp has and continues to induce others to infringe the '430 patent by, including without limitation, encouraging Ariosa to perform the HarmonyTM Prenatal Test, and will continue to do so, unless and until enjoined by this Court.

30. On information and belief, LabCorp has and continues to contributorily infringe the '430 patent by, including without limitation, supplying to Ariosa material components of the HarmonyTM Prenatal Test having no substantial non-infringing use, and will continue to do so, unless and until enjoined by this Court.

31. Defendants' infringement of the '430 patent has injured Plaintiffs in their business and property rights. Plaintiff Verinata is entitled to recovery monetary damages for such injuries pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

32. Defendants' infringement of the '430 patent has caused irreparable harm to Plaintiff Verinata and will continue to cause such harm unless and until their infringing activities are enjoined by this Court.

PRAAYER FOR RELIEF

WHEREFORE, Verinata and Stanford pray for relief as follows:

Verinata and Stanford

A. Judgment that Defendants have infringed, induced others to infringe, and/or contributorily infringed the '076 patent;

B. An order permanently enjoining Defendants from further infringement of the '076 patent;

C. An award of damages pursuant to 35 U.S.C. § 284;

D. An order for an accounting of damages from Defendants' infringement;

E. An award of enhanced damages, up to and including trebling of the damages awarded to Verinata and Stanford;

F. An award to Verinata and Stanford of their costs and reasonable expenses to the fullest extent permitted by law;

G. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs; and

H. An award of such other and further relief as the Court may deem just and proper.

Verinata Only

I. Judgment that Defendants have infringed, induced others to infringe, and/or contributorily infringed the '430 patent:

J. An order permanently enjoining Defendants from further infringement of the '430 patent;

¹⁰ An award of damages pursuant to 35 U.S.C. § 284;

I. An order for an accounting of damages from Defendants' infringement:

M. An award of enhanced damages, up to and including trebling of the damages awarded to Verinata;

N An award to Verinata of its costs and reasonable expenses to the fullest

1 extent permitted by law;

2 O. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and
3 an award of attorneys' fees and costs; and

4 P. An award of such other and further relief as the Court may deem just and
5 proper.

6

7 **DEMAND FOR JURY TRIAL**

8 Pursuant to Federal Rule of Civil Procedure 38(b) and Civil Local Rule 3-6(a),
9 Verinata and Stanford hereby demand a trial by jury on all issues so triable.

10 Dated: November 29, 2012

11 Respectfully submitted,

12 WEIL, GOTSHAL & MANGES LLP
13 Edward R. Reines
14 Derek C. Walter
15 Michele A. Gauger

16 By: /s/ Edward R. Reines
17 Edward R. Reines
18 Attorneys for Plaintiffs
19 VERINATA HEALTH, INC.
20 and
21 THE BOARD OF TRUSTEES OF
22 THE LELAND STANFORD
23 JUNIOR UNIVERSITY